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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,150	07/07/2003	Stephen Flynn	H310816USCOM	6778
28079	7590	07/13/2006		
GOWLING, LAFLEUR HENDERSON LLP ONE MAIN STREET WEST HAMILTON, ON L8P 4Z5 CANADA			EXAMINER LOPEZ, AMADEUS SEBASTIAN	
			ART UNIT 3743	PAPER NUMBER

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/613,150	Applicant(s) FLYNN, STEPHEN	
	Examiner Amadeus S. Lopez	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/31/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the one-way valve in the inlet of the air bag must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "34" has been used to designate both container receiver

Art Unit: 3743

and central aperture. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities:

In paragraph 17, in lines 2 and 4, the word "duct" should be deleted and replaced with -- duck --. Appropriate correction is required.

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In line 2 of the abstract, the legal phraseology often used in patent claims, "said" is used.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. **Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6276363 to Gray in view of US Patent No. 4374521 to Nelson et al.**
6. **With regards to claim 1**, what is taught and shown by Gray in Figs. 1-2 is a manually-operable resuscitator operable also to inject medication into air being supplied to a patient, said resuscitator having: a resiliently compressible air bag (1) having an inlet (2) and an outlet (3) and a patient valve (19) through which air flows in passing from the bag to the patient, the patient valve having a one-way valve member through which air flows in passing from the bag to the patient, and the patient valve also having a passage extending from the atmosphere to the interior thereof (passage between outlet 27 and patient valve 19) adjacent to the one-way valve member and upstream

thereof through which medication can be injected into the air (from nebulizer 100; Col. 2, lines 24-30) as it passes from the bag to the one-way valve member. What is not taught and shown by is the inlet having a one-way valve through which air passes into the bag from the atmosphere. What is taught by Nelson et al. is a manually operable resuscitator (20) in which the inlet (Fig. 1 where oxygen supply valve 24 is inserted into bag fill valve assembly 26) has a one-way valve (26) through which air passes into the bag from the atmosphere (although the bag is attached to an oxygen source, it is inherently capable of drawing air into the bag by compressing and releasing the bag manually; further it is disclosed within Col. 3, lines 47-51 that it is well known in the art to use just atmospheric air to provide gas to a user). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the manually operable resuscitator of Gray to include a one-way valve in the inlet of the resuscitation bag through which air passes into the bag from the atmosphere or oxygen source as taught by Nelson et al. in order to control how much and when air or oxygen enters the bag.

7. **With regards to claim 2**, what is taught and shown by Gray in Figs. 1-2 is a resuscitator (1) wherein the passage is provided with a one-way valve (19) through which medication (from nebulizer 100) passes.

8. **With regards to claim 3**, what is taught and shown by in Figs. 1-2 is a resuscitator with all the limitations of claim 3 with the exception of wherein the patient valve (19) causes air from the bag to turn 90 degrees to pass through the one-way valve member and the passage is located so as to inject medication into the air in a

direction substantially parallel to the direction of flow of the air through the one-way valve member. What is taught by Gray is a resuscitator wherein the patient valve (19) causes air from the bag to pass straight through the one-way valve member and is located so as to inject medication into the air substantially perpendicular to the direction of the air through the one-way valve member. After reviewing the specification, the examiner has concluded that the applicant never establishes any criticality for having the patient valve cause the air from the bag turn 90 degrees to pass through the one-way valve member and have the passage located so as to inject medication into the air in a direction substantially parallel to the direction of flow of the air through the one-way valve member. Therefore it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to have the patient valve configured to make air from the resuscitation bag either turn 90 degrees or pass straight through the one way valve with the passage located so as to inject medication into the air in a direction substantially parallel or perpendicular to the direction of flow through the valve because both are effective means for the aerosolization of medicament for the delivery to a user.


Conclusion

9. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure. US 5357946, US 6158428, US 5842467, and US 6340023.

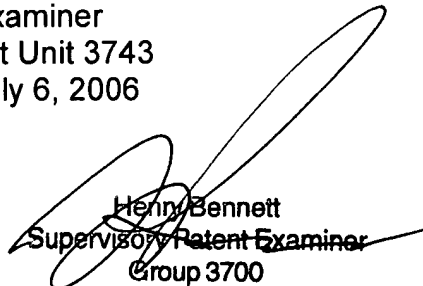
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Amadeus S Lopez
Examiner
Art Unit 3743
July 6, 2006

ASL


Henry Bennett
Supervisory Patent Examiner
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